REMARKS

Status of the Claims

Claims 1, 3, 5-7, 9-15, 17, 19, 21 and 48-50 are pending in the application, claims 2, 4, 8, 16, 18, 20 and 22-47 having been canceled.

Support for the amendment to claim 1 can be found, for example, in paragraphs [0009]-[0015]. In this regard, see 2173.05(i) ("If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims").

Withdrawal of Rejection under 35 U.S.C. § 112, first paragraph

Applicant notes, with thanks, the withdrawal of the rejection of claims 1, 3, 5-7, 9-15, 17, 19-21 and 46-50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Withdrawal of Rejection under 35 U.S.C. § 103(a)

Applicant notes, with thanks, the withdrawal of the rejection of claims 1, 3, 5-7, 9-15, 17, 19-21 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al., US 6,153,252 (Hossainy) in view of Bolz, US 6,287,332 B1 (Bolz).

Rejection under 35 U.S.C. § 103(a)

Claims 1, 3, 5-7, 9-15, 17, 19-21 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al., US 6,153,252 (Hossainy) in view of Bolz, US 6,287,332 B1 (Bolz) and Igaki et al., US 6,045,568 (Igaki). Applicant respectfully traverses this rejection.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' " *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn* , 441 F.3d 977, 988,

(Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. "When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' … Thus, 'obviousness requires a suggestion of all limitations in a claim.' …" *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

According to the Office Action, Hossainy is deficient in that Hossainy fails to disclose the biodegradable inner core material is specifically selected from biodegradable metallic or ceramic materials. The Office Action, however, turns to Bolz, urging that it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz, because doing so would provide advantageous mechanical properties (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.).

The composite device proposed by the Examiner can also be described as the application of polymer coating as described in Hossainy to a biodegradable metallic stent as taught in Bolz.

Regardless, there would be no reason to provide a coating in accordance with Hossainy on a stent in accordance with Bolz, and in fact, there would be reasons *not* to apply such a coating.

In this regard, the primary reason for applying a polymer coating to a metallic stent is to create a reservoir for a therapeutic agent (metals are not typically good reservoir materials). The presently claimed invention, however, is not directed to devices of this type and in fact expressly excludes therapeutic agents.

It is true that another potential function of a polymeric coating would be to regulate the degradation rate of an underlying biodegradable inner core material, and that is in fact the subject matter of the present claims. However, to use applicants invention as motivation would be improper hindsight. See MPEP 2142 ("impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art").

Moreover, Bolz teaches that degradation rate may be controlled using other available methods, specifically: (a) by controlling the ratio of the metallic elements within an alloy stent. See col. 3, lines 43-44 and (b) by controlling the size of the surface of contact between a

substantially pure corrodible stent body (e.g., zinc) and a local electrode connected thereto or by the selection of the element forming the local electrode (e.g., a gold electrode) (in other words, analogous to the principle behind galvanized materials). See Col. 3, lines 36-58 and Example 2. Thus, there is no reason to use a coating for purposes of controlling degradation.

On the other hand, there are reasons to avoid the use of polymer coatings, particularly where there are no compelling reasons to include them in a given device (e.g., therapeutic agent release), including the fact that many polymeric materials are known to induce foreign body responses upon implantation. In this regard, see Willem J. van der Giessen et al., "Marked Inflammatory Sequelae to Implantation of Biodegradable and Nonbiodegradable Polymers in Porcine Coronary Arteries," *Circulation.* 1996;94: 1690-1697 (of record) ("An array of both biodegradable and nonbiodegradable polymers has been demonstrated to induce a marked inflammatory reaction within the coronary artery with subsequent neointimal thickening…") See also U.S. 4,613,517, which notes at col. 1, lines 20-24, that while polymers may have become preferred materials for prosthetic devices, a major drawback of many of these materials is their thrombogenicity. See further US 2008/0091262. ("Various byproducts of degradation of biodegradable polymers are known to incite an inflammatory response.")

Moreover, even assuming for the sake of argument that a biodegradable polymer can be selected from Hossainy that does not provoke a foreign body response, one would not add a coating of such a material to a biodegradable stent without good reasons for doing so. In this regard, the addition of such a coating would add to manufacturing cost and complexity. Another issue with adding materials to implants, is the fact that such added materials would have to undergo regulatory scrutiny prior to use.

Igaki does not make up for the above deficiencies in Hossainy and Bolz. In fact, Igaki teaches away from the hypothetical stent constructed in the Office Action whereby Hossainy's inner core is formed from a biodegradable metallic material as taught by Bolz. In this regard, Igaki teaches that metallic stents are hard and that they consequently tend to stress the vessel, producing inflammation or hypertrophy in the vessel which can cause reconstriction in the vessel (col. 1, 29-32). The metallic materials taught by Botz are also hard and thus would tend to stress the vessel, producing inflammation or hypertrophy in the vessel.

For at least the foregoing reasons, the presently claimed invention is patentable over Hossainy, Bolz and Igaki.

Reconsideration and withdrawal of the rejection under 35 USC 103(a) are respectfully requested.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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